REMARKS

The present invention relates to methods for the treatment of a subject having an infirmity such as cancer. Invention methods are broadly applicable to the administration of a wide variety of pharmacologically active agents, and can be implemented by a variety of routes of administration. Invention methods comprise administering to a subject a sub-therapeutic dose level of a pharmacologically active agent (such as the anticancer agent paclitaxel) effective against a variety of cancers over an administration period sufficient to achieve a therapeutic effect. Sub-therapeutic dose levels contemplated for use in the practice of the present invention subject recipients to substantially less active agent than is typically employed; generally comprising in the range of about 1% up to about 20% of the conventionally administered amount of said pharmacologically active agent.

By the present communication, claims 1, 11 and 13-15 have been amended to define Applicants' invention with greater particularity. This amendment does not introduce new matter as it is fully supported throughout the specification and claims as originally filed. Accordingly, Claims 1-5 and 7-21 remain pending in this application. The present status of all claims in the application is provided in the Listing of Claims presented herein beginning on page 2.

Rejections under 35 U.S.C. §102(b)

The rejection of claims 1-4, 9-12, and 14-21 under 35 U.S.C. §102(b) as allegedly being anticipated by WO 94/06422 (Wilson et al.), is once again respectfully traversed.

Applicants' invention, as defined for example by claim 1, distinguishes over Wilson et al. by requiring treatment of a subject having cancer by administering to the subject a sub-therapeutic dose level of a pharmacologically active agent effective against the cancer, wherein sub-therapeutic dose levels comprise in the range of about 1% up to about 20% of the

conventionally administered amount of said pharmacologically active agent, and wherein the sub-therapeutic dose is administered over an extended administration time (e.g., in the range from about 7 days to about 1 year). Wilson et al. do not disclose or suggest such an administration protocol.

In contrast, the dose levels contemplated by Wilson et al. (i.e., 70-140 mg/m^2) are much higher than contemplated by the present claims---the Wilson dosage represents in the range of about 50% to greater than 100% of the conventionally administered amount of the active agent (paclitaxel), which typically falls in the range of about 135-175 mg/m^2 (see, for example, the sentence bridging pages 7 and 8 of Applicants' specification). In addition, the "long term" administration of paclitaxel contemplated by Wilson et al. is no greater than 96 hours (barely half the minimum administration period of 7 days required by the present claims).

Rejections under 35 U.S.C. §103(a)

The rejection of claims 5-8 and 13 under 35 U.S.C. §103(a) as allegedly being unpatentable over Wilson et al., is once again respectfully traversed.

Applicants' invention, as defined for example by claim 5, distinguishes over Wilson et al. by requiring treatment of a subject having cancer by locally administering to the subject a sub-therapeutic dose level of a pharmacologically active agent effective against the cancer, wherein sub-therapeutic dose levels comprise in the range of about 1% up to about 20% of the conventionally administered amount of said pharmacologically active agent, and wherein the sub-therapeutic dose is locally administered over an extended administration time (e.g., in the range from about 7 days to about 1 year). Wilson et al. do not disclose or suggest such an administration protocol.

In contrast, Wilson et al. contemplate systemic (as opposed to local) administration of paclitaxel at dosage levels (i.e., 70-140 mg/m^2) which are much higher than contemplated by the present claims—the Wilson dosage represents in the range of about 50% to greater than 100% of the conventionally administered amount of the active agent (paclitaxel), which typically falls in the range of about 135-175 mg/m^2 (see, for example, the sentence bridging pages 7 and 8 of Applicants' specification). In addition, the "long term" administration of paclitaxel contemplated by Wilson et al. is no greater than 96 hours (barely half the minimum administration period of 7 days required by the present claims).

Conclusion

In view of the above amendments and remarks, prompt and favorable action on all claims is respectfully requested. In the event any issues remain to be resolved in view of this communication, the Examiner is invited to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

Respectfully submitted,

Date: February 11, 2005 By _____

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